01/29/2010

Considered

Approved for use through 07/31/2012, OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Substitute for form 1449/PTO 10/575,745 Application Number INFORMATION DISCLOSURE Filing Date April 9, 2007 STATEMENT BY APPLICANT First Named Inventor Yigal M. Pinto Art Unit 1641 (Use as many sheets as necessary) Examiner Name G. W. Counts BYG-101 Sheet 6 Attorney Docket Number

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, When Relevant Passages or Relevar Figures Appear
/GC/	A1	US-20030032030	02-13-2003	Prolla et al.	
1	A2	US-20040110221	06-10-2004	Twine et al.	
	АЗ	US-20050084915	04-21-2005	Woo	
	A4	US-20050106100	05-19-2005	Harris et al.	
	A5	US-20060019235	01-26-2006	Soen et al.	
_	A6	US-20060019890	01-26-2006	Kapoun et al.	
	A7	US-20060141493		West et al.	
_	A8	US-20060246496		Ahmed et al.	
$\neg$	A9	US-20060257946	11-16-2006	Ding et al.	
\ /	A10	US-20070082332	04-12-2007	Mendrick et al.	
V	A11	US-20070092886	04-26-2007	Tabibiazar et al.	
/GC/	A12	US-20070105105	05-10-2007	Clelland et al.	
		1			1
					1

	FOREIGN PATENT DOCUMENTS						
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	Г	
Examiner Initials*	No.1	Country Code <sup>5</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (# known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages Or Relevant Figures Appear	T	
/GC/	B1	WO-0157274-A2	08-09-2001	Molecular Dynamics Inc et al.		Г	
	B2	WO-0177389-A2	10-18-2001	Incyte Genomics Inc et al.		П	
	B3	WO-03031650-A2	04-17-2003	Bayer Ag et al.			
1/	B4	WO-03071279-A1	08-28-2003	Zarita Biotech Co Ltd et al.		г	
$\neg \mathbf{v}$	B5	WO-2004038376-A2	05-06-2004	Univ Duke et al.		г	
/GC/	B6	WO-2004048933-A2	06-10-2004	Wyeth Corp et al.		г	

"EXAMINE" relial if inference considered, whether or not clastin is noteromance with MPEP 600. Done then through estation first in conformance and not condered. Include capy of the form within the communication to replace "CTE" (IN 2016 replaces replaced to the marked with mis ninge sections (I'm ninge sections (I'm ninge sections (I'm ninge sections) (I'm ninge s
the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must
precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.15 if
possible. 5 Applicant is to place a check mark here if English language Translation is attached.

Examiner

/Gary Counts/

01/29/2010

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERC

- 011	del the Laperwork Heddollon	101 01 1	aas, no peraona are required to r	sapono to a conection of illion	nation unless it contains a valid only control number	
Sut	FORMATION DISCLOSURE			Complete if Known		
				Application Number	10/575,745	
l II	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Filing Date	April 9, 2007	
l s				First Named Inventor	Yigal M. Pinto	
				Art Unit	1641	
	(Use as many sheets as necessary)			Examiner Name	G. W. Counts	
Sheet	2	of	6	Attorney Docket Number	BYG-101	

			U.S. PA	FENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
-					
_					
_					

	FOREIGN PATENT DOCUMENTS						
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,		
Initials*	No.	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (# known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages Or Relevant Figures Appear	Te	
/GC/	B7	WO-2004063334-A2	07-29-2004	Gene Logic Inc et al.		Г	
/GC	B8	WO-2004111654-A2	12-23-2004	Ciphergen Biosystems Inc et al.		Г	
/GC/	B9	WO-2005023314-A1	03-17-2005	Squibb Bristol Myers Co et al.		Г	
/GC/	B10	WO-2005070446-A1	08-04-2005	Scios Inc et al.		Г	
/GC/	B11	WO-2006026074-A2	03-09-2006	Univ Duke et al.		Г	
/GC	B12	WO-2006083986-A2	08-10-2006	Us Health et al.			

\*EXAMINE:\* Initial inference considered, whether or not clustion in a conformance with METE 900. Date line heavy butter. In not in conformance and not considered include copy of the form white net communication to applicant. \*\*CTER\*\* ONE.\* These applications which was missined which are ninger extends in the Cite No. are not supplied (under 37 CFR\*\*) 169((12)(3))) because that application was fleet after June 30, 2003 of a nonlable in the TW. \*\*Applicants in the Cite No. are not supplied (under 37 CFR\*\*) 169((12)(3))) because that application was fleet after June 30, 2003 of a nonlable in the TW. \*\*Applicants in the Cite No. \*\*Applicants in the C

Examiner

/Gary Counts/

PTOSS(980 to 70.09)
Approved for use through 07.01.02(0.000 601.000)
Approved for use through 07.01.02(0.000 601.000)
U.S. Patient and Trademack Officer, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1996, no persons are required to respond to a collection of information unless a contains a valid MOSI confort number

				•	
Sul	stitute for form 1449/PTO				Complete if Known
				Application Number	10/575,745
l II	NFORMATION	I DI	SCLOSURE	Filing Date	April 9, 2007
l s	STATEMENT BY APPLICANT			First Named Inventor	Yigal M. Pinto
-				Art Unit	1641
	(Use as many sh	eets a	s necessary)	Examiner Name	G. W. Counts
Sheet	3	of	6	Attorney Docket Number	BYG-101

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the flem (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/GC/	C1	Ahmed et al. (2007) "Advanced glycation endproducts: what is their relevance to diabetic complications?" Diabetes, Obesity and Metabolism 9(3): 233-245.	
/GC/	C2	Aragno et al. (2005) "Up-Regulation of Advanced Glycated Products Receptors in the Brain of Diabetic Rats is Prevented by Antioxidant Treatment," Endocrinology 146(12): 5561-5567.	
/GC/	СЗ	Aragno et al. (2006) "Oxidative Stress-Dependent Impairment of Cardiac-Specific Transcription Factors in Experimental Diabetes," Endocrinology 147(12): 5967-5974.	
/GC/	C4	Bender MedSystems product information and manual for enzyme-linked immunosorbent assay for quantitative detection of human Galectin-3, BMS279/2, dated August 24, 2006, 32 pages.	
/GC/	C5	Bohlender et al. (2005) "Advanced glycation end products and the kidney," American Journal of Physiology: Renal Physiology 289: F645-F659.	П
/GC/	C6	Cameselle-Teijeiro et al. (2005) "Cystic Tumor of the Atrioventricular Node of the Heart Appears to Be the Heart Equivalent of the Solid Cell Nests (Ultimobranchial Rests) of the Thyroid," American Journal of Clinical Pathology 123(3): 369-375.	
/GC/	C7	Cheng Weng et al. (2007) "Differential neuroprotective effects of a minocycline-based drug cocktail in transient and permanent local cerebral ischemia," <a href="Experimental Neurology">Experimental Neurology</a> 204(1): 433-442.	
/GC	C8	lurisci et al. (2000) "Concentrations of Galectin-3 in the Sera of Normal Controls and Cancer Patients," Clinical Cancer Research 6:1389-1393.	
/GC	С9	Kankova et al. (2005) "Haplotype analysis of the RAGE gene: identification of a haplotype marker for diabetic nephropathy in type 2 diabetes mellitus," Nephrology, Dialysis, Transplantation 20(6): 1093-1102.	
/GC	C10	Karlsen et al. (2006) "Immune-mediated beta-cell destruction in vitro and in vivo - A pivotal role for galectin-3," Biochemical and Biophysical Research Communications 344(1): 406-415.	

Examiner Signature	/Gary Counts/	Date Considered	01/29/2010

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

'Applicant's unique citation designation number (optional), ''Applicant is to place a check mark here if English language Translation is attached.

BYG-101

PTOSSIGNE, 07-09,
Approved for use through 07/10/20/20.048 0651-0031
U.S. Patern and Tackmank Office, U.S. DEPARTMENT OF COMMERCE
Under the Papervork Reduction Act of 1995, no persons are required to respond to a collection of infermation unless a Contains a value ONDs central number Complete if Known Substitute for form 1449/PTO Application Number 10/575.745 INFORMATION DISCLOSURE Filing Date April 9, 2007 STATEMENT BY APPLICANT Yigal M. Pinto First Named Inventor Art Unit 1641 (Use as many sheets as necessary) Examiner Name G. W. Counts

Attorney Docket Number

Sheet

of

6

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/GC/	C11	Liehn et al. (2005) "CCR5-but not CCR1-deficiency protects against neointima formation in apolipoprotein E-deficient mice," European Heart Journal 26(Suppl 1): 239.	
/GC	C12	Lok et al. (2007) "Galectin-3, a Novel Marker of Macrophage Activity, Predicts Outcome in Patients with Stable Chronic Heart Ffailure," <u>Journal of the American College of Cardiology</u> 49(9) Suppl. A: 98A.	
/GC/	C13	Mensah-Brown et al. (2006) "Functional Capacity of Macrophages Determines the Induction of Type 1 Diabetes," Annals of the New York Academy of Sciences 1084: 49-57.	
/GC/	C14	Mita et al. (2007) "Swings in blood glucose levels accelerate atherogenesis in apolipoprotein E-deficient mice," Biochemical and Biophysical Research Communications 358(3): 679-685.	
/GC	C15	Moore et al. (2005) "Using Peripheral Blood Mononuclear Cells to Determine a Gene Expression Profile of Acute Ischemic Stroke: A Pilot Investigation," <u>Circulation</u> 111(2): 212- 221.	
/GC	C16	Papaspyridonos et al. (2006) "A Potential Role for Galectin-3 in Atherosclerotic Plaque Progression through Monocyte Chemoattraction and Macrophage Activation" <u>Atherosclerosis</u> 186(2): S3.	
/GC/	C17	Pieters (2006) "Inhibition and Detection of Galectins," Chem Bio Chem 7:721-728.	$\overline{}$
/GC/	C18	Pugliese et al. (2006) "Increased Glomerular Cell (Podocyte) Apoptosis in Rats with Streptozotocin-induced Diabetes Mellitus: Relation to Increased p53 Expression," <u>Diabetologia</u> 49(Suppl 1): 651-652.	
/GC/	C19	Reifenberg et al. (2007) "Interferon-gamma Induces Chronic Active Myocarditis and Cardiomyopathy in Transgenic Mice," American Journal of Pathology 171(2): 463-472.	
/GC	C20	Schroen et al. (2003) "Genomic analysis identifies Thrombospondin-2 as a molecular predictor of heart failure," Circulation 108(17 Suppl.):IV-260.	

Examiner	/Gary Counts/	Date	01/20/2010
Signature	/Gary Counts/	Considered	01/29/2010

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

BYG-101

PTOSSIGNE, 07-09,
Approved for use through 07/10/20/20.048 0651-0031
U.S. Patern and Tackmank Office, U.S. DEPARTMENT OF COMMERCE
Under the Papervonk Reduction Act of 1995, no persons are required to respond to a collection of infermation unless a Contains a value ONDs central number Complete if Known Substitute for form 1449/PTO Application Number 10/575.745 INFORMATION DISCLOSURE April 9, 2007 Filing Date STATEMENT BY APPLICANT Yigal M. Pinto First Named Inventor Art Unit 1641 (Use as many sheets as necessary) Examiner Name G. W. Counts

Attorney Docket Number

Sheet

5

of

6

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/GC/	C21	Schroen et al. (2007) "Lysosomal Integral Membrane Protein 2 is a Novel Component of the Cardiac Intercalated Disc and Vital for Load-induced Cardiac Myccyte Hypertrophy," <u>Journal of Experimental Medicine</u> 204(5): 1227-1235.	
/GC/	C22	Sharma et al. (2003) "Galectin-3 is a novel macrophage derived mediateor of cardiac firbrosis and specifically marks failing hearts," Circulation 108(17 Suppl.):IV-260.	
/GC/	C23	Sharma et al. (2004) "Galectin-3 Marks Activated Macrophages in Failure-Prone Hypertrophied Hearts and Contributes to Cardiac Dysfunction," <u>Circulation</u> 110:3121-3128.	
/GC/	C24	Sharma et al. (2005) "Early growth regulator-1 mediates galectin-3 induced cardiac fibrosis," <u>Hypertension</u> 46(4): 819-820.	
/GC/	C25	Sharma et al. (2005) "Mice lacking galectin-3 exhibit preserved cardiac function and decreased fibrosis following angiotensin II infusion," Circulation 112(17) Suppl S: II-64.	
/GC	C26	Sharma et al. (2007) "Novel Anti-inflammatory Mechanisms of Ac-SDKP in High Blood Pressure-induced Target Organ Damage," Circulation 114(18) Suppl S: 240.	П
/GC/	C27	Shirakata et al. (2001) Inverse regulation of the angiogenesis factor VEGF and the angiogenesis inhibitors Thrombospondin-1 and TSP-2 in human epidermal keratinocytes," Journal of Investigative Dermatology 117(2):391.	
/GC/	C28	Stitt et al. (2005) "Impaired Retinal Angiogenesis in Diabetes: Role of Advanced Glycation End Products and Galectin-3," <u>Diabetes</u> 54(3): 785-794.	
/GC/	C29	Tan et al. (2007) "AGE, RAGE and ROS in Diabetic Neuropathy," Seminars in Nephrology 27(2): 130-143.	
/G0	<sub>С</sub> 30	Tang et al. (2007) "National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines; Clinical Utilization of Cardiac Biomarker Testing in Heart Failure," <u>Circulation</u> 116(5): 999-e109.	

Signature	/Gary Counts/	Considered	01/29/2010

<sup>\*</sup>EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

PTOSSIGNE, 07-09,
Approved for use through 07/10/20/20.048 0651-0031
U.S. Patern and Trademack Office, U.S. DEPARTMENT OF COMMERCE
Under the Papervook Reduction Act of 1995, no persons are required to respond to a collection of infermation unless a Contains a value ONDs central number

Substitute for form 1449PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use as many sheets as necessary)				Complete if Known		
				Application Number	10/575,745	
				Filing Date	April 9, 2007	
				First Named Inventor	Yigal M. Pinto	
				Art Unit	1641	
				Examiner Name	G. W. Counts	
Sheet	6	of	6	Attorney Docket Number	BYG-101	

Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T'
/GC/	C31	van Kimmenade et al. (2005) "Galectin-3 predicts 60 days mortality in heart failure: A step towards multimarker strategy in heart failure. Results from the ProBNP investigation of dyspnea in the emergency department (PRIDE) study," Circulation 112(17) Suppl S: II-669.	
/GC/	C32	van Kimmenade et al. (2006) "Utility of Amino-Terminal Pro-Brain Natriuretic Peptide, Galectin-3, and Applin for the Evaluation of Patients With Acute Heart Failure," <u>Journal of the</u> American College of Cardiology 48(6):1217-1224.	
/GC/	C33	Walton et al. (2003) "Thrombospondin-2 and lymphotoxin-alpha gene variations predict coronary heart disease in a large prospective study," <u>Circulation</u> 108(17 Suppl.):IV-260.	
			E
			E

Examiner Signature	/Gary Counts/	Date Considered	01/29/2010

<sup>\*</sup>EXAM/NER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&#</sup>x27;Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.